

WHAT IS CLAIMED IS:

1. A stent comprising a tubular stent matrix of which diameter is extendable and a flexible polymer layer coating said stent matrix, wherein

5 said polymer layer is closely attached to and covers the entire surface of the stent matrix.

2. A stent as claimed in claim 1, wherein said stent matrix is a mesh metallic member.

3. A stent as claimed in claim 2, wherein said mesh metallic
10 member is made of cobalt-chromium-nickel-iron alloy.

4. A stent as claimed in claim 2, wherein said mesh metallic member is made of nickel-titanium alloy.

5. A stent as claimed in any one of claims 1 through 4, wherein said polymer layer is provided with a plurality of fine pores formed
15 therein.

6. A stent as claimed in claim 5, wherein said fine pores are spaced from each other at substantially equal intervals.

7. A stent as claimed in claim 5 or 6, wherein said fine pores are spaced from each other at intervals of from 51 to 10000 μm and each
20 pore has a diameter of from 5 to 500 μm .

8. A stent as claimed in any one of claims 1 through 7, wherein said polymer layer is made of segmented polyurethane.

9. A stent as claimed in any one of claims 1 through 7, wherein said polymer layer is made of a polymer of polyolefin series.

25 10. A stent as claimed in any one of claims 1 through 7, wherein said polymer layer is a polymer film of silicone series.

11. A stent as claimed in any one of claims 1 through 10, wherein the thickness of said polymer layer is from 10 to 100 μm .

12. A stent as claimed in any one of claims 1 through 11, wherein said polymer layer is coated with a biodegradable polymer.

13. A stent as claimed in claim 12, wherein said biodegradable polymer contains a drug.

5 14. A stent as claimed in claim 13, wherein said drug is selected from a group consisting of heparin, low-molecular heparin, hirudin, argatroban, formacolin, vapirost, prostamoline, prostakilin homolog, dextran, D-phe-pro-arg chloromethyl ketone, dipyridamole, platelet
10 receptor antagonist of glycoprotein, recombinant hirudin, thrombin inhibitor, vascular heptyne, angiotensin-converting enzyme inhibitor, steroid, fibrocyte growth factor antagonist, fish oil, omega 3 fatty acid, histamine, antagonist, HMG-CoA reductase inhibitor, seramin, serotonin
15 blocker, thioprotease inhibitor, triazolopyrimidine, interferon, vascular endothelial growth factor (VEGF), rapamycin, FK506, mevalotin, and fuluvastatin.

15 15. A process of producing a stent having a tubular stent matrix of which diameter is extendable and flexible polymer films which are attached to both the inner periphery and the outer periphery of said stent matrix and have a plurality of fine pores formed therein, said process
20 comprising:

 a step of forming a polymer film for outer layer by rotating a mold having a cylindrical inner bore about its axis and also supplying a liquid resin material into the mold;

 a step of supplying said stent matrix into said mold;

25 a step of forming a polymer film for inner layer by rotating the mold about its axis and also supplying a liquid resin material into the mold;

 a step of releasing the stent matrix with the films from the mold.

16. A process of producing a stent as claimed in claim 15,
wherein the polymer film for outer layer is made of a base polymer only.

17. A process of producing a stent as claimed in claim 15,
wherein the step of forming a polymer film for outer layer comprises
5 forming a first polymer film for outer layer made of a biodegradable
polymer and, after that, forming a second polymer film for outer layer
made of a base polymer on the inner side of the first polymer film.

18. A process of producing a stent as claimed in any one of
claims 15 through 17, wherein said polymer film for inner layer is made
10 only of a base polymer.

19. A process of producing a stent as claimed in any one of
claims 15 through 17, wherein the step of forming a polymer film for
inner layer comprises forming a first polymer film for inner layer made
of a base polymer and, after that, forming a second polymer film for
15 inner layer made of a biodegradable polymer on the inner side of the
first polymer film.

20. A process of producing a stent as claimed in claim 15,
wherein the polymer film for outer layer and the polymer film for inner
layer are made of a base polymer only, and
20 after the removal of the mold, the stent matrix with the outer and
inner films is impregnated into a liquid resin material of biodegradable
polymer so as to form a coating layer of the biodegradable polymer.

21. A process of producing a stent as claimed in any one of
claims 16 through 18, wherein the base polymer is a segmented
25 polyurethane polymer.

22. A process of producing a stent as claimed in any one of
claims 15 through 21, further including a step of perforating the polymer
film on an intermediate product released from the mold.

23. A process of producing a stent as claimed in claim 22,
wherein the perforation is conducted by laser.

24. A process of producing a stent as claimed in any one of
claims 15 through 23, wherein the fine pores are formed at substantially
5 equal intervals.

25. A process of producing a stent having a tubular stent matrix
of which diameter is extendable and flexible polymer films which are
attached to both the inner periphery and the outer periphery of said stent
matrix and have a plurality of fine pores formed therein, said process
10 comprising:

a step of forming the polymer film by impregnating a mandrel
into a liquid resin material for forming the polymer film and pulling up
the mandrel; and

a step of equalizing the thickness of the polymer film by pulling
15 up the mandrel in the vertical direction and controlling the pulling-up
speed.

26. A process of producing a stent as claimed in claim 25,
wherein the pulling-up speed is gradually lowered.

27. A process of producing a stent as claimed in claim 25 or 26,
20 wherein the polymer film is made of a base resin material only.

28. A process of producing a stent as claimed in claim 25 or 26,
wherein the polymer film comprises a base layer made of a base resin
material and a layer of a biodegradable polymer covering the surface of
the base layer.

25 29. A process of producing a stent as claimed in claim 27 or 28,
wherein the liquid base resin material is a solution of segmented
polyurethane polymer.

30. A process of producing a stent as claimed in any one of

claims 25 through 29, wherein said fine pores are formed after the polymer film is formed.

31. A process of producing a stent as claimed in claim 30, wherein said fine pores are formed by laser machining.

5 32. A process of producing a stent having a tubular stent matrix of which diameter is extendable and flexible polymer films which are attached to both the inner periphery and the outer periphery of said stent matrix and have a plurality of fine pores formed therein, said process comprising:

10 a step of inserting a polymer film for inner layer into the stent matrix and overlaying a polymer film for outer layer onto the stent matrix; and

 a step of welding the respective polymer films to the stent matrix.

15 33. A process of producing a stent as claimed in claim 32, wherein the welding is conducted by heating the respective polymer films.

 34. A process of producing a stent as claimed in claim 32, wherein the respective polymer films are welded to the stent matrix by heating the stent matrix with high-frequency dielectric heating.

20 35. A process of producing a stent as claimed in claim 32, wherein the respective polymer films are welded to the stent matrix by heating the stent matrix with Joule heat.

 36. A process of producing a stent as claimed in claim 32, wherein the respective polymer films and the stent matrix are welded by
25 supersonic vibration.

 37. A process of producing a stent as claimed in claim 32, wherein the polymer films are welded to the stent matrix by hot isostatic pressing.

38. A process of producing a stent as claimed in claim 32, wherein the polymer films are welded to the stent matrix by using a heat shrinkable film.

5 39. A process of producing a stent as claimed in any one of claims 32 through 38, wherein the respective polymer films and the stent matrix are pressurized from both sides during the welding.

40. A process of producing a stent as claimed in claim 39, wherein the pressurization is conducted by inserting a mandrel to the polymer film for inner layer and applying pressures to the polymer film
10 for outer layer in radial direction toward the middle line.

41. A process of producing a stent as claimed in any one of claims 32 through 40, further including a step of perforating the polymer film of an intermediate product which is formed by welding the polymer films to the stent matrix.

15 42. A process of producing a stent as claimed in claim 41, wherein the perforation is conducted by laser.

43. A process of producing a stent as claimed in claim 41 or 42, wherein the fine pores are formed at substantially equal intervals.

20 44. A process of producing a stent as claimed in any one of claims 32 through 43, wherein the polymer films are tubular.

45. A process of producing a stent as claimed in any one of claims 32 through 44, wherein said polymer films are coated with a biodegradable polymer.

25 46. A process of producing a stent as claimed in any one of claims 24, 30, 31, and 43 through 45, wherein said fine pores are spaced from each other at intervals of from 51 to 10000 μm and each pore has a diameter of from 5 to 500 μm .

47. A process of producing a stent as claimed in any one of

claims 15 through 46, wherein the thickness of said polymer films is from 10 to 100 μm .

48. A process of producing a stent as claimed in any one of claims 15 through 47, wherein said stent matrix is a mesh metallic member.

49. A process of producing a stent as claimed in any one of claims 19 through 24, 28 through 31, and 45 through 48, wherein said biodegradable polymer contains a drug.

50. A process of producing a stent as claimed in claim 49, wherein said drug is selected from a group consisting of heparin, low-molecular heparin, hirudin, argatroban, formacolin, vapiprost, prostamoline, prostakilin homolog, dextran, D-phe-pro-arg chloromethyl ketone, dipyridamole, platelet receptor antagonist of glycoprotein, recombinant hirudin, thrombin inhibitor, vascular heptyne, angiotensin-converting enzyme inhibitor, steroid, fibrocyte growth factor antagonist, fish oil, omega 3 fatty acid, histamine, antagonist, HMG-CoA reductase inhibitor, seramin, serotonin blocker, thioprotease inhibitor, triazolopyrimidine, interferon, vascular endothelial growth factor (VEGF), rapamycin, FK506, mevalotin, and fluvastatin.

51. A stent produced by a process claimed in any one of claims 15 through 50.

52. A stent comprising a plurality of stent matrixes of which diameter is extendable and polymer films which are attached to both the inner peripheries and the outer peripheries of said stent matrixes and have a plurality of fine pores formed therein, wherein said stent matrixes are aligned in the longitudinal direction thereof and are united by the polymer films.

53. A stent as claimed in claim 52, wherein the stent matrixes are

independent from each other.

54. A stent comprising a plurality of stent matrixes which are aligned in the longitudinal direction thereof at intervals, a cylindrical outer polymer film which is overlaid on the outer peripheries of said stent matrixes, and a cylindrical inner polymer film which is laid on the inner peripheries of said stent matrixes, wherein said stent matrixes are united by the outer polymer film and the inner polymer film, wherein

the outer polymer film and the inner polymer film allow the shift of the stent matrixes relative to the polymer films during expansion of the stent matrixes, and

the outer polymer film and the inner polymer film are bonded to each other at portions between adjacent stent matrixes.

55. A stent as claimed in any one of claims 52 through 54, wherein said stent matrixes are mesh metallic members.

56. A stent as claimed in claim 54 or 55, wherein said outer polymer film and said inner polymer film are not bonded to said stent matrixes.

57. A stent as claimed in claim 55 or 56, wherein said outer polymer film and said inner polymer film are partially bonded to each other at meshes of the stent matrixes composed of said mesh metallic members.

58. A stent as claimed in claim 57, wherein said outer polymer film and said inner polymer film are bonded in the dot form.

59. A stent as claimed in claim 54 or 55, wherein said outer polymer film and said inner polymer film are partially bonded to said stent matrixes.

60. A stent as claimed in claim 59, wherein said outer polymer film and said inner polymer film are bonded to said stent matrixes in the

dot form.

61. A stent as claimed in any one of claims 54 through 60, wherein said outer polymer film and said inner polymer film are flexible polymer films each having a plurality of fine pores.

5 62. A stent as claimed in any one of claims 55 through 61, wherein at portions where said outer polymer film and said inner polymer film are not bonded to said stent matrixes and said outer polymer film and said inner polymer film are not bonded to each other, spaces between said outer polymer film and said inner polymer film are
10 filled with one or more selected from a group consisting of physiologically active substances, radioactive substances, and magnetic substances.

63. A stent comprising a stent matrix composed of a mesh tube of which diameter is extendable, a cylindrical outer polymer film overlaid
15 on the outer periphery of said stent matrix, and a cylindrical inner polymer film laid on the inner periphery of said stent matrix, wherein said outer polymer film and said inner polymer film are not bonded to said stent matrix and are bonded to each other at least at some of meshes of said mesh stent matrix.

20 64. A stent as claimed in claim 63, wherein said outer polymer film and said inner polymer film are bonded to each other in the dot form.

65. A stent as claimed in claim 63, wherein after said outer polymer film and said inner polymer film are bonded to each other in the
25 dot form, the bonded portions are perforated.

66. A stent as claimed in any one of claims 63 through 65, wherein said outer polymer film and said inner polymer film are flexible polymer films having fine pores formed therein.

67. A stent as claimed in any one of claims 63 through 66,
wherein at a portion where said outer polymer film and said inner
polymer film are not bonded to each other, a space between said outer
polymer film and said inner polymer film are filled with one or more
5 selected from a group consisting of physiologically active substances,
radioactive substances, and magnetic substances.

68. A stent as claimed in any one of claims 52 through 67,
wherein said polymer films are coated with a biodegradable polymer.

69. A stent as claimed in claim 68, wherein said biodegradable
10 polymer contains a drug.

70. A stent as claimed in claim 69, wherein said drug is selected
from a group consisting of heparin, low-molecular heparin, hirudin,
argatroban, formacolin, vapiprost, prostamoline, prostakilin homolog,
dextran, D-phe-pro-arg chloromethyl ketone, dipyridamole, platelet
15 receptor antagonist of glycoprotein, recombinant hirudin, thrombin
inhibitor, vascular heptyne, angiotensin-converting enzyme inhibitor,
steroid, fibrocyte growth factor antagonist, fish oil, omega 3 fatty acid,
histamine, antagonist, HMG-CoA reductase inhibitor, seramin, serotonin
blocker, thioprotease inhibitor, triazolopyrimidine, interferon, vascular
20 endothelial growth factor (VEGF), rapamycin, FK506, mevalotin, and
fuluvastatin.

71. A stent as claimed in any one of claims 52, 53, 61, 62, and
66-70, wherein said fine pores are arranged at substantially equal
intervals.

25 72. A stent as claimed in claim 71, wherein said fine pores are
spaced from each other at intervals of from 51 to 10000 μm and each
pore has a diameter of from 5 to 500 μm .

73. A stent as claimed in any one of claims 52 through 72,

wherein said polymer films are made of segmented polyurethane.

74. A stent as claimed in any one of claims 52 through 73,
wherein the thickness of said polymer films is from 10 to 100 μm .

75. A stent as claimed in any one of claims 52 through 74,
5 wherein said polymer films are coated with a biodegradable polymer.

76. A stent as claimed in claim 75, wherein said biodegradable
polymer contains a drug.

77. A stent as claimed in claim 76, wherein said drug is selected
from a group consisting of heparin, low-molecular heparin, hirudin,
10 argatroban, formacolin, vapiprost, prostamoline, prostakilin homolog,
dextran, D-phe-pro-arg chloromethyl ketone, dipyridamole, platelet
receptor antagonist of glycoprotein, recombinant hirudin, thrombin
inhibitor, vascular heptyne, angiotensin-converting enzyme inhibitor,
steroid, fibrocyte growth factor antagonist, fish oil, omega 3 fatty acid,
15 histamine, antagonist, HMG-CoA reductase inhibitor, seramin, serotonin
blocker, thioprotease inhibitor, triazolopyrimidine, interferon, vascular
endothelial growth factor (VEGF), rapamycin, FK506, mevalotin, and
fuluvastatin.